Translation

PCT/JP2003/015836

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3127WO0P	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/JP2003/015836	International filing date (*day/month/year*) 11 December 2003 (11.12.2003)	Priority date (*day/month/year*) 12 December 2002 (12.12.2002)
International Patent Classification (IPC) or national classification and IPC A61K 38/17, 31/7088, 39/395, 45/00, 48/00, A61P 13/12		
Applicant TAKEDA PHARMACEUTICAL COMPANY LIMITED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☒ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) DISC 1, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 15 January 2004 (15.01.2004)	Date of completion of this report 17 December 2004 (17.12.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

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International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1 (the parts other than the parts using the EDG-5 receptor), 2-21

because:

☒ the said international application, or the said claim No. 20 relates to the following subject matter which does not require an international preliminary examination *(specify)*:

The invention of claim 20 concerns a method for treating the human body by therapy, which does not require an examination by the International Preliminary Examining Authority in accordance with PCT Article 34(4)(a)(i) and Rule 67.1(iv).

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1 (the parts other than the parts using the EDG-5 receptor), 2-21 .

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ see Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

This examination finds that the following 18 inventions are described in the above claims.

(1) The parts of claim 1 using the EDG-2 receptor
(2) The parts of claim 1 using the EDG-3 receptor
(3) The parts of claim 1 using the EDG-5 receptor
(4) The parts of claims 2 and 3 concerning the EDG-2 receptor
(5) The parts of claims 2 and 3 concerning the EDG-3 receptor
(6) The parts of claims 2 and 3 concerning the EDG-5 receptor
(7) The parts of claims 4 and 5 concerning the EDG-2 receptor
(8) The parts of claims 4 and 5 concerning the EDG-3 receptor
(9) The parts of claims 4 and 5 concerning the EDG-5 receptor
(10) The parts of claims 6 and 7 concerning the EDG-2 receptor
(11) The parts of claims 6 and 7 concerning the EDG-3 receptor
(12) The parts of claims 6 and 7 concerning the EDG-5 receptor
(13) The parts of claims 8, 9, 14 and 21 concerning [1]
(14) The parts of claims 10, 11, 15, and 21 concerning [2]
(15) The parts of claims 12, 13, 16, and 21 concerning [3]
(16) The parts of claims 17-19 concerning the EDG-2 receptor and the parts of claim 21 concerning the EDG-2 receptor of [4]
(17) The parts of claims 17-19 concerning the EDG-3 receptor and the parts of claim 21 concerning the EDG-3 receptor of [4]
(18) The parts of claims 17-19 concerning the EDG-5 receptor and the parts of claim 21 concerning the EDG-5 receptor of [4]

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claim No. 1 (the parts using the EDG-5 receptor).

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Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claim	1	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claim	1	NO
Industrial applicability (IA)	Claim	1	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Claim 1 (Part using the EDG-5 receptor)

Document 1: WO 02/077642 A1
Document 2: Katsuma S et al. Pharmacogenomics J. 2001; 1(3): 211-7

Documents 1 and 2 cited in the international search report describe the relationship between EDG-5 and IgA nephropathy. More specifically, document 1 describes a process for screening for drugs for the prevention and treatment of proliferative glomerulonephritis based on the action of inhibiting binding of the Edg-5 ligand to the Edg-5 receptor. This examination finds that persons skilled in the art can easily obtain drugs for the prevention and treatment of proliferative glomerulonephritis based on that document, and that binding between the Edg-5 ligand and Edg-5 [receptor?] is competitively inhibited by adding the EDG-5 receptor, thus providing an effect for the prevention and treatment of proliferative glomerulonephritis.

As a result, based on the descriptions in documents 1 and 2, the part of the invention of claim 1 that uses the EDG-5 receptor does not involve an inventive step.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:

   a. type of material

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material

   ☐ in written format

   ☒ in computer readable form

   c. time of filing/furnishing

   ☐ contained in the international application as filed

   ☒ filed together with the international application in computer readable form

   ☐ furnished subsequently to this Authority for the purpose of search and/or examination

   ☐ received by this Authority as an amendment* on _____

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

** If item 4 in Box No. I applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".*

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of Box IV:

Items (1) to (3)

The invention of claim 1 concerns an agent for the prevention and treatment of diabetic nephropathy, chronic renal failure...containing the EDG-2 receptor, EDG-3 receptor, EDG-5 receptor, and partial peptides or salts thereof.

In this instance, as described in page 12, line 27 to page 13, line 12 of the Specification of this application, each of these receptors is a publicly known substance. In addition, after referring to the description in WO 02/077642 A1, etc., this examination finds that each of these receptors do not necessarily have common properties and activity when used as a drug. Therefore, this examination finds that items (1) to (3) are not technically related such that they contain a "special technical feature" and do not satisfy the requirement for unity of invention.

Items (4) to (12)

The "amino acid sequence, partial peptide, or salt thereof" (claim 1), polynucleotide (claims 2 and 3), "antibody" (claims 4 and 5), and the "polynucleotide containing a complementary base sequence or portion thereof" (claims 6 and 7) are each different substances. Therefore, this examination finds that preventative/diagnostic agents and diagnostic agents using the same are not technically related such that they contain a "special technical feature" and do not satisfy the requirement for unity of invention.

Items (13) to (18)

In consideration of the fact that WO 02/077642 is public knowledge, this examination finds that items (1) to (3) and (13) to (18) are not technically related such that they contain a "special technical feature" and do not satisfy the requirement for unity of invention.